



03CO 0590

Dkt. No. 51320-AA/JPW/SHS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Graham P. Allaway, et al.
Serial No. : 09/724,105
Filed : June 25, 2001
For : USES OF A CHEMOKINE RECEPTOR FOR
INHIBITING HIV-1 INFECTION

1185 Avenue of the Americas
New York, New York 10036
August 10, 2001

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

INFORMATION DISCLOSURE STATEMENT

In accordance with their duty of disclosure under 37 C.F.R. §1.56, applicants direct the Examiner's attention to the following references which are listed on the PTO-1449 form attached hereto as **Exhibit A**.

1. U.S. Serial No. 5,021,409 issued June 4, 1991, issued to Murrer et al.;
2. U.S. Serial No. 5,126,433, issued June 30, 1992, Maddon et al.;
3. U.S. Patent No. 5,440,021, filed February 25, 1994, issued August 5, 1995, Anan Chuntharapai, et al.
4. U.S. Patent No. 5,504,003, filed March 8, 1994, issued April 2, 1996, Haodong Li, et al.
5. Alkhatib, Ghalb, et al., (1996) "CC CKR5: A RANTES, MIP-1 α , MIP-1 β Receptor as a Fusion Cofactor for Macrophage-Tropic

Applicants : Graham P. Allaway, et al.
Serial No. : 09/724,105
Filed : June 25, 2001
Page 2

HIV-1" *Science* 272:1955-1958;

6. Alkhatib et al. (1997), HIV-1 Co-receptor Activity Of CCR5 And Its Inhibition By Chemokines: Independence From G Protein Signaling And Importance Of Coreceptor Downmodulation, Virology 234:340-348;
7. Arenzana-Selsdedos, Fernando, et al., (1996) "HIV blocked by chemokine antagonist" *Nature* 383:400;
8. Berger et al., (1999), Chemokine Receptors As HIV-1 Co-receptors: Roles In Viral Entry, Tropism, And Disease Ann. Rev. Immun. 17:657-700;
9. Bleul, Conrad, C., et al., (1996) "The lymphocyte chemoattractant SDF-1 is a ligand for LESTR/fusion and blocks HIV-1 entry" *Nature* 382:829-832;
10. Brenner, T.J., et al., (1991) "Relation between HIV-1 syncytium inhibition antibodies and clinical outcome in children" *The Lancet* 337:1001-1005;
11. Choe, Hyeryun, et al., (1996) "The β -Chemokine Receptors CCR3 and CCR5 Facilitate Infection by Primary HIV-1 Isolates" *Cell* 85:1135-1148;
12. Cocchi, Florenza, et al., (1995) "Identification Of RANTES, MIP-1 α , and MIP-1 β as the Major HIV-Suppressive Factors Produced by CD8⁺ T Cells" *Science* 270: 1811-1815;
13. Daar et al., (1990), High Concentrations Of Recombinant Soluble CD4 Are Required To Neutralize Primary Human Immunodeficiency Virus Type I Isolates, Proc.Nat'l.

Applicants : Graham P. Allaway, et al.
Serial No. : 09/724,105
Filed : June 25, 2001
Page 3

Acad.Sci. 87:6574-6578;

14. De Clercq et al. (1992), Potent And Selective Inhibition Of Human Immunodeficiency Virus (HIV)-1 And HIV-2 Replication By A Class Of Bicyclams Interacting With A Virus Uncoating Event, Proc.Natl.Acad.Sci. 89: 5286-5290;
15. De Clercq, et al.,(1994) "Highly potent and selective inhibition of human immunodeficiency virus by the bicyclam derivative JM3100" *Antimicrobial Agents and Chemotherapy* 38(4):668-674
16. De Clercq, E., (1995) "Antiviral therapy for human immunodeficiency virus infections" *Clinical Microbiology Reviews* 8(2):200-239;
17. Deng et al.,(1996), Identification Of A Major Co-receptor For Primary Isolates Of HIV-1, Nature 381:661-666;
18. Doranz, et al., (1996) "A dual-tropic primary HIV-1 isolate that uses fusin and the β -chemokine receptors CKR-5, CKR-3, and CKR-2b as fusin cofactors" *Cell* 85:1149-1158;
19. Doranz et al. (1997), A Small-Molecule Inhibitor Directed Against The Chemokine Receptor CXCR4 Prevents Its Use As An HIV-1 Co-receptor, J. Exp. Med. 186(8): 1395-1400;
20. Dragic, T. et al. (1996) "HIV-1 entry into CD4+ cells is mediated by the chemokine receptor CC-CKR-5" *Nature* 381:667-673;
21. Fahey et al., (1992) Status Of Immune-based Therapies In HIV Infection And AIDS, Clin. Exp. Immunol. 88:1-5;

Applicants : Graham P. Allaway, et al.
Serial No. : 09/724,105
Filed : June 25, 2001
Page 4

22. Feng et al., (1996) HIV-1 Entry Cofactor: Functional cDNA Cloning Of A Seven-Transmembrane, G Protein-Coupled Receptor, Science 272:872-877;
23. Fox et al., (1994) No Winners Against AIDS, Bio. Tech. 12:128;
24. Gong, Jiang-Hong, et al., (1995) "Antagonists Of Monocyte Chemoattractant Protein 1 Identified By Modification Of Functionally Critical NH₂-terminal Residues" *J. Exp. Med.* 181:631-640;
25. Gong, Jiang-Hong, et al., (1996) "RANTES and MCP-3 Antagonists Bind Multiple Chemokine Receptors" *The Journal of Biological Chemistry* 371:10521-10527;
26. Haynes et al., (1996), Update On The Issues Of HIV Vaccine Development, Ann. Med. 28:39-41;
27. Hattori, T., et al., (1989) "Involvement of tryptase-related cellular protease(s) in human immunodeficiency virus type 1 infection" *FEB* 248:48-52;
28. Jones, Simon, A., et al., (1997) "Chemokine Antagonists That Discriminate between Interleukin-8 Receptors" *The Journal of Biological Chemistry* 272:16166-16169;
29. Klotman, et al., (1995) "Transgenic models of HIV-1" *AIDS* 9(4)313-324;
30. Levy, (1996) Controlling HIV Pathogenesis: The Role Of The Noncytotoxic Anti-HIV Response Of CD8+ T Cells, Immunology Today 17: 217-224;

Applicants : Graham P. Allaway, et al.
Serial No. : 09/724,105
Filed : June 25, 2001
Page 5

31. Oellerich, M., (1984), Enzyme-Immunoassay: A Review, J.Clin. Chem. Clin. Biochem. 22(12): 895-904;
32. Litwin, et al., (1996) "Human immunodeficiency virus type 1 membrane fusin mediated by a laboratory-adapted strain and a primary isolate analyzed by resonance energy transfer" *Journal of Virology* 70(9):6437-6441;
33. McKnight, Aine, et al., (1997) "Inhibition of Human Immunodeficiency Virus Fusion by a Monoclonal Antibody to a Coreceptor (CXCR4) Is both Cell Type and Virus Strain Dependent" *Journal of Virology* 71(2): 1692-1696;
34. Moser, Bernhard, et al., (1993) "Interleukin-8 Antagonists Generated by N-terminal Modification" *The Journal of Biological Chemistry* 268:7125-7128;
35. Oberlin, Estelle, et al., (1996) "The CXC chemokine SDF-1 is the ligand for LESTR/fusion and prevents infection by T-cell-line-adapted HIV-1" *Nature* 382:833-835;
36. Raport, Carol, J., et al., (1996) "New members of the chemokine receptor gene family" *Journal of Leukocyte Biology* 59:18-23;
37. Samson, M. et al., (1996), Molecular Cloning And Functional Expression Of A New Human CC-chemokine Receptor Gene, Biochemistry 35: 3362-3367;
38. Scarlatti et al., (1997), In Vivo Evolution Of HIV-1 Co-receptor Usage And Sensitivity To Chemokine-mediated Suppression, Nature Medicine 3(11): 1259-1265;

Applicants : Graham P. Allaway, et al.
Serial No. : 09/724,105
Filed : June 25, 2001
Page 6

39. Simmons, Graham, et al., (1997) "Potent Inhibition of HIV-1 Infectivity in Macrophages and Lymphocytes by a Novel CCR5 Antagonist" *Science* 276:276-279;
40. Szabo, et al., (1992) "CD4 changes conformation upon ligand binding" *The Journal of Immunology* 149(11):3596-3604;
41. Trkola, Alexandra, et al., (1996) "CD4-dependent, antibody-sensitive interactions between HIV-1 and its co-receptor CCR-5" *Nature* 384:184-187;
42. Wells, Timothy, N.C., et al., (1996) "Selectivity and antagonism of chemokine receptors" *Journal of Leukocyte Biology* 59:53-60;
43. Wu, Lijun, et al., (1996) "CD4-induced interaction of primary HIV-1 gp120 glycoproteins with the chemokine receptor CCR-5," *Nature* 384:179-183;
44. Wu, Lijun, et al., (1997) "CCR5 Levels and Expression Pattern Correlate with Infectability by Macrophage-tropic HIV-1, In Vitro" *J. Exp. Med.* 185:1681-1691;
45. Zhang, Y,J., et al., (1994) "Structure/Activity Analysis of Human Monocyte Chemoattractant Protein-1 (MCP-1) by Mutagenesis," *The Journal of Biological Chemistry* 269:15918-15924;

Applicants : Graham P. Allaway, et al.
Serial No. : 09/724,105
Filed : June 25, 2001
Page 7

The subject application is a continuation application of U.S. Serial No. 08/874,618, filed June 13, 1997. The above listed references 1, 6, 8, 14, 19, 30, 31, 37, 38 were submitted and considered by the United States Patent and Trademark Office in an Information Disclosure Statement filed January 19, 2001 in connection with U.S. Serial No. 08/874,618. The above listed references 3-5, 7, 9, 10-12, 15, 16, 18, 20, 24, 25, 27, 28, 29, 32-36, 39-45 were submitted to and considered by the United States Patent and Trademark Office in an Information Disclosure Statement filed January 4, 1999 in connection with U.S. Serial No. 08/874,618. The above listed references 2, 13, 17, 20-23 and 26 were cited in an Office Action issued September 2, 1998 in connection with U.S. Serial No. 08/874,618. Accordingly, under 37 C.F.R. §1.98(d) copies of these references are not required to be provided to the United States Patent and Trademark Office, since they were previously cited by, or submitted to, the United States Patent and Trademark Office in an application relied upon for an earlier filing date under 35 U.S.C. §120.

Summary

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone either of them at the number provided below.

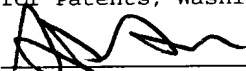
Applicants : Graham P. Allaway, et al.
Serial No. : 09/724,105
Filed : June 25, 2001
Page 8

Pursuant to 37 C.F.R. §1.97(b)(3), no fee is deemed necessary in connection with the filing of this Information Disclosure Statement. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125

Respectfully submitted,



I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

 8/10/01
John P. White Date
Reg. No. 28,678
Spencer H. Schneider
Reg. No. 45,923

John P. White
Registration No. 28,678
Spencer H. Schneider
Registration No. 45,923
Attorneys for Applicant(s)
Cooper & Dunham, LLP
1185 Avenue of the Americas
New York, New York 10036
(212) 278-0400

Form PTO-1449

U.S. Department of Commerce
Patent and Trademark Office

Atty. Docket No.

51320-AA/JPW/SHS

Serial No.

09/724,105

INFORMATION DISCLOSURE CITATION
(Use several sheets if necessary)

Applicants

Graham P. Allaway et al.

Filing Date

June 25, 2001

Group

U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
US	5 4 4 0 0 2 1	8/5/94	A. Chuntharapai, et al.			
US	5 5 0 4 0 0 3	4/2/96	H. Li et al.			
US	5 0 2 1 4 0 9	6/4/91	Murrer et al.			
US	5 1 2 6 4 3 3	6/30/92	Maddon et al.			

FOREIGN PATENT DOCUMENTS

	Document Number	Date	Country	Class	Subclass	Translation	
						Yes	No

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	Alkhatib, Ghalb, et al., (1996) "CC CKR5: A RANTES, MIP-1 α , MIP-1 β Receptor as a Fusion Cofactor for Macrophage-Tropic HIV-1" <i>Science</i> 272:1955-1958;
	Arenzana-Selsdedos, Fernando, et al., (1996) "HIV blocked by chemokine antagonist" <i>Nature</i> 383:400;
	Bleul, Conrad, C., et al., (1996) "The lymphocyte chemoattractant SDF-1 is a ligand for LESTR/fusion and blocks HIV-1 entry" <i>Nature</i> 382:829-832;
	Brenner, T.J., et al. (1991) "Relation between HIV-1 syncytium inhibition antibodies and clinical outcome in children" <i>The Lancet</i> 337:1001-1005;
	Choe, Hyeryun, et al., (1996) "The β -Chemokine Receptors CCR3 and CCR5 Facilitate Infection by Primary HIV-1 Isolates" <i>Cell</i> 85:1135-1148;
	Cocchi, Florenza, et al., (1995) "Identification Of RANTES, MIP-1 α , and MIP-1 β as the Major HIV-Suppressive Factors Produced by CD8 ⁺ T Cells" <i>Science</i> 270: 1811-1815;
	De Clercq, et al., (1994) "Highly potent and selective inhibition of human immunodeficiency virus by the bicyclam derivative JM3100" <i>Antimicrobial Agents and Chemotherapy</i> 38(4):668-674;
	De Clercq, E., (1995) "Antiviral therapy for human immunodeficiency virus infections" <i>Clinical Microbiology Reviews</i> 8(2):200-239;
	Doranz, et al., (1996) "A dual-tropic primary HIV-1 isolate that uses fusin and the β -chemokine receptors CKR-5, CKR-3, and CKR-2b as fusin cofactors" <i>Cell</i> 85:1149-1158;

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. next communication to applicant.

Applicants: Graham P. Allaway et al.
Serial No. : 09/724,105
Filed: June 25, 2001
Exhibit A

Form PTO-1449

U.S. Department of Commerce
Patent and Trademark Office

Atty. Docket No.

51320-AA/JPW/SHS

Serial No.

09/724,105

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

Applicants

Graham P. Allaway et al.

Filing Date

June 25, 2001

Group

U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
	US 5 4 4 0 0 2 1	8/5/94	A. Chuntharapai, et al.			
	US 5 5 0 4 0 0 3	4/2/96	H. Li et al.			
	US 5 0 2 1 4 0 9	6/4/91	Murrer et al.			
	US 5 1 2 6 4 3 3	6/30/92	Maddon et al.			

FOREIGN PATENT DOCUMENTS

Document Number	Date	Country	Class	Subclass	Translation
					Yes No

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	Alkhatib, Ghalb, et al., (1996) "CC CKR5: A RANTES, MIP-1 α , MIP-1 β Receptor as a Fusion Cofactor for Macrophage-Tropic HIV-1" <i>Science</i> 272:1955-1958;
	Arenzana-Selsdedos, Fernando, et al., (1996) "HIV blocked by chemokine antagonist" <i>Nature</i> 383:400;
	Bleul, Conrad, C., et al., (1996) "The lymphocyte chemoattractant SDF-1 is a ligand for LESTR/fusion and blocks HIV-1 entry" <i>Nature</i> 382:829-832;
	Brenner, T.J., et al. (1991) "Relation between HIV-1 syncytium inhibition antibodies and clinical outcome in children" <i>The Lancet</i> 337:1001-1005;
	Choe, Hyeryun, et al., (1996) "The β -Chemokine Receptors CCR3 and CCR5 Facilitate Infection by Primary HIV-1 Isolates" <i>Cell</i> 85:1135-1148;
	Cocchi, Florenza, et al., (1995) "Identification Of RANTES, MIP-1 α , and MIP-1 β as the Major HIV-Suppressive Factors Produced by CD8 ⁺ T Cells" <i>Science</i> 270: 1811-1815;
	De Clercq, et al.,(1994) "Highly potent and selective inhibition of human immunodeficiency virus by the bicyclam derivative JM3100" <i>Antimicrobial Agents and Chemotherapy</i> 38(4):668-674;
	De Clercq, E., (1995) "Antiviral therapy for human immunodeficiency virus infections" <i>Clinical Microbiology Reviews</i> 8(2):200-239;
	Doranz, et al., (1996) "A dual-tropic primary HIV-1 isolate that uses fusin and the β -chemokine receptors CKR-5, CKR-3, and CKR-2b as fusin cofactors" <i>Cell</i> 85:1149-1158;

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-1449

U.S. Department of Commerce
Patent and Trademark Office

Atty. Docket No.

51320-AA/JPW/SHS

Serial No.

09/724,105

INFORMATION DISCLOSURE CITATION
(Use several sheets if necessary)

Applicants

Graham P. Allaway et al.

Filing Date

June 25, 2001

Group

U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate

FOREIGN PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS														
		Document Number							Date	Country	Class	Subclass	Translation	
		Yes	No											

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	Dragic, T. et al., (1996) "HIV-1 entry into CD4+ cells is mediated by the chemokine receptor CC-CKR-5" <i>Nature</i> 381:667-673;
	Gong, Jiang-Hong, et al., (1995) "Antagonists Of Monocyte Chemoattractant Protein 1 Identified By Modification Of Functionally Critical NH ₂ -terminal Residues" <i>J. Exp. Med.</i> 181:631-640;
	Gong, Jiang-Hong, et al., (1996) "RANTES and MCP-3 Antagonists Bind Multiple Chemokine Receptors" <i>The Journal of Biological Chemistry</i> 371:10521-10527;
	Hattori, T., et al., (1989) "Involvement of tryptase-related cellular protease(s) in human immunodeficiency virus type 1 infection" <i>FEB</i> 248:48-52;
	Jones, Simon, A., et al., (1997) "Chemokine Antagonists That Discriminate between Interleukin-8 Receptors" <i>The Journal of Biological Chemistry</i> 272:16166-16169;
	Klotman, et al., (1995) "Transgenic models of HIV-1" <i>AIDS</i> 9(4)313-324;
	Litwin, et al., (1996) "Human immunodeficiency virus type 1 membrane fusin mediated by a laboratory-adapted strain and a primary isolate analyzed by resonance energy transfer" <i>Journal of Virology</i> 70(9):6437-6441;
	McKnight, Aine, et al., (1997) "Inhibition of Human Immunodeficiency Virus Fusion by a Monoclonal Antibody to a Coreceptor (CXCR4) Is both Cell Type and Virus Strain Dependent" <i>Journal of Virology</i> 71(2): 1692-1696;
	Moser, Bernhard, et al., (1993) "Interleukin-8 Antagonists Generated by N-terminal Modification" <i>The Journal of Biological Chemistry</i> 268:7125-7128;

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-1429

U.S. Department of Commerce
Patent and Trademark Office

Atty. Docket No.

51320-AA/JPW/SHS

Serial No.

09/724,105

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

Applicants

Graham P. Allaway et al.

Filing Date

June 25, 2001

Group

U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate

FOREIGN PATENT DOCUMENTS

Document Number	Date	Country	Class	Subclass	Translation	
					Yes	No

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	Oberlin, Estelle, et al., (1996) "The CXC chemokine SDF-1 is the ligand for LESTR/fusion and prevents infection by T-cell-line-adapted HIV-1" <i>Nature</i> 382:833-835;
	Raport, Carol, J., et al., (1996) "New members of the chemokine receptor gene family" <i>Journal of Leukocyte Biology</i> 59:18-23;
	Simmons, Graham, et al., (1997) "Potent Inhibition of HIV-1 Infectivity in Macrophages and Lymphocytes by a Novel CCR5 Antagonist" <i>Science</i> 276:276-279;
	Szabo, et al., (1992) "CD4 changes conformation upon ligand binding" <i>The Journal of Immunology</i> 149(11):3596-3604;
	Trkola, Alexandra, et al., (1996) "CD4-dependent, antibody-sensitive interactions between HIV-1 and its co-receptor CCR-5" <i>Nature</i> 384:184-187;
	Wells, Timothy, N.C., et al., (1996) "Selectivity and antagonism of chemokine receptors" <i>Journal of Leukocyte Biology</i> 59:53-60;
	Wu, Lijun, et al., (1996) "CD4-induced interaction of primary HIV-1 gp120 glycoproteins with the chemokine receptor CCR-5," <i>Nature</i> 384:179-183;
	Wu, Lijun, et al., (1997) "CCR5 Levels and Expression Pattern Correlate with Infectability by Macrophage-tropic HIV-1, In Vitro" <i>J. Exp. Med.</i> 185:1681-1691;
	Zhang, Y.J., et al., (1994) "Structure/Activity Analysis of Human Monocyte Chemoattractant Protein-1 (MCP-1) by Mutagenesis," <i>The Journal of Biological Chemistry</i> 269:15918-15924;

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.